Welcome to the weekly newsletter from the Center for Addiction Research! Each newsletter includes highlights from addiction in the news topics, active funding opportunities offered by NIDA/NIAAA, and information about any new publications from CAR members. Please email Jen Rowe (roweji@ucmail.uc.edu) to change your communication preferences. Thank you.

Thank you for your interest in the Center for Addiction Research - our mission is to accelerate scientific progress in the prevention and treatment of substance use disorders and their consequences by fostering research collaborations across: 1) UC departments, colleges, and centers including Cincinnati Children's Hospital Medical Center; 2) Local, regional, and state community and governmental partners; and 3) Other academic institutions and industry."



UC/ Regional News

Why American Rescue Plan Must Be Used Effectively To Address Kentucky's Addiction Crisis.

In an opinion for the Louisville (KY) Courier-Journal (9/9, 554K), contributors Tim Robinson, Nancy Hale and Beth Davisson write that Kentucky "has a unique opportunity on the horizon that may forever change how we address addiction-related issues." They explain that a study from the NORC Walsh Center for Rural Health Analysis and the University of Kentucky Center of Excellence in Rural Health "points to several contributing factors associated with the region's decline in drug overdose deaths, including increased access to substance use disorder treatment, the development of a recovery ecosystem, prevention and education around substance use disorder, and the existence of strong partnerships, coalitions and collaborations throughout the state." They add that Kentucky must ensure funds from the American Rescue Plan "are allocated properly to have the most meaningful impacts and allow more Kentuckians to obtain long-term recovery" based on the "solid framework" established by this report. The National Institute on Drug Abuse is mentioned.

Ohio Judge Ready To "Save Lives" With Ohio's Updated Casey's Law.

The Cincinnati Enquirer (9/2, DeMio, 223K) reports that "a Hamilton County judge wants families who have loved ones with addiction to know there is a new avenue

available to them in his court to get them treatment." Ohio's version of Casey's Law, a civil involuntary treatment option, "requires a Probate Court order, and Judge Ralph Winkler said Thursday he's ready to get started considering cases – and helping people get the treatment they need." He said, "I don't like that it's called involuntary treatment. My hope is that once people start using the law, it will become cooperative with the people who need the help."

Mike St. John Speaks To Inmates At Mcdc About 'Road 2 Recovery'.

The Richmond (KY) Register (9/7, Six, 12K) reports on Michael St. John who "was born in Corbin, Kentucky," and struggled with "addiction and hopelessness." After a suicide "attempt, St. John entered the Hope Center's emergency services and slept on a mat where he prayed to God and stated he was ready to change his life and was willing to work with His plan." St. John "has been sober since June 1, 2016." Now, he "is teaming up with others inside the Madison County Detention Center to help those incarcerated with substance abuse disorder through the 'Road 2 Recovery' program." The county "is one of the 16 Kentucky counties participating in the HEALing Communities Study, which aims to reduce opioid overdose deaths by 40% in participating communities that represent more than a third of Kentucky's population."

Giant Eagle loses bid to escape Ohio opioid claims

(Reuters) - Supermarket and pharmacy chain Giant Eagle has lost a bid to escape claims by two Ohio counties that it fueled opioid addiction by ignoring red flags that prescriptions were being used for illegal sales. The <u>order</u> Wednesday by U.S. District Judge Dan Polster in Cleveland, Ohio, means Giant Eagle will face trial next month alongside Walgreens Boots Alliance and Walmart Inc. Rite Aid Corp, which had also been a defendant in the case, recently settled. The trial will serve...

Meigs Health Matters... Addressing substance abuse, mental health

According to the 2019 Ohio State Health Assessment, overall wellbeing for Ohioans has declined. Trends in premature death, life expectancy and overall health status indicate that the health of Ohioans has worsened. Unintentional injuries (including drug overdose) were leading causes of premature death in 2017. Mental health and addiction ... continue to be significant challenges in Ohio. Ohio's performance on these priorities has worsened or remained unchanged in recent...

Court Weighs Drug Distributor's Insurance Coverage Fight

COLUMBUS, Ohio (AP) — The Ohio Supreme Court is deciding whether the insurance company for a drug distributor should be forced to provide a legal defense in the company's fight against government lawsuits related to the opioid epidemic. The Wednesday court hearing will be focused on a dispute between Hamilton County-

based Masters Pharmaceutical and its insurer for eight years from 2010 to 2018, <u>Wisconsin</u>-based Acuity Insurance. Beginning in 2012...

National News

Substance Abuse On Campus: Challenges Confronting First-Year Students.

Inside Sources (9/7, Matton) reports first-year college students "face challenges that increase their risk of alcohol and drug abuse," and "over time, these challenges can lead to addiction." It is "not always easy to enter a new social environment," and "to fit in, many students start abusing alcohol or other drugs." Many students in college "live with mental health conditions such as anxiety, depression, post-traumatic stress disorder, and schizophrenia." Inside Sources adds that "according to the National Institute on Drug Abuse, about half of people with mental health conditions develop drug addiction."

College Students' Marijuana Use Hit Highs In 2020, Alcohol Use Saw 'Significant' Decrease, Study Shows.

USA Today (9/8, Cannon, 12.7M) reports, "Marijuana use among U.S. college students hit a historic high in 2020, while alcohol use might have taken a pandemic-induced dip," investigators concluded in the "National Institute on Drug Abuse's annual 'Monitoring the Future' study." In the meantime, "alcohol use was less common among college students than in previous years," showing "decreases from 2019 in terms of binge drinking, getting drunk and overall alcohol use." These "changes in substance use came as COVID-19 forced college students to navigate social distancing measures, online classes and an overall muted version of normal campus life," which, "for some students...was fully remote" last year. NIDA Director Dr. Nora Volkow said in a news release, "It will be critical to investigate how and when different substances are used among this young population, and the impact of these shifts over time."

Medical Cannabis Unlikely To Benefit Most Chronic Pain Patients.

STAT (9/8, Cueto, 262K) reports "medical cannabis might be a helpful therapy for some people who have chronic pain, but it's unlikely to benefit most, according to new clinical guidelines published Wednesday in the journal BMJ." The guidelines, created "by an international group of researchers who analyzed three dozen medical cannabis studies, say there isn't enough evidence that medical marijuana products help most patients suffering from chronic pain, so they shouldn't be widely recommended for such people." Because "cannabis is classified in the U.S. as a Schedule I Controlled Substance...the National Institutes of Health's 'hands have been tied' when it comes to funding research on medical cannabis, [Judith A. Paice, director of the Cancer Pain Program at Northwestern University's Feinberg School of Medicine,] said."

JAMA Study Finds "Little Evidence" Of Link Between Cannabis Legalization And Youth Use.

CannabisWire (9/7, Martin) reports new research conducted by investigators from the Department of Agricultural Economics and Economics at Montana State University has "found 'little evidence' that adult and medical use cannabis legalization 'encourage youth marijuana use.'" The researchers "updated previous research by expanding their dataset from the Youth Risk Behavior Survey to include 1993 through 2019." The authors "called into 'question the generalizability of their results' from a previous study that looked at data only until 2017." The findings were published Monday in the JAMA Network Open. NIDA Director Dr. Nora Volkow is mentioned.

VA Sending Mixed Messages For Vets About Cannabis Use To Treat PTSD.

The Columbia (MO) Missourian (9/7, 17K) reports that "while the VA has embraced the federally illegal status of" marijuana, "agency policy does not allow discrimination against veterans who acquire medical cards in states where it is allowed, although those who do get their MMJ cards do so with their own resources and at their own risk outside the purview of the Veterans Health Administration." However, "that isn't always the case, said Derek Debus, an Arizona attorney." He "said having rules in place doesn't guarantee fair treatment for veterans who legally use cannabis." Debus added, "Instead of just sitting on the sidelines, the VA is affirmatively pushing this mythology that cannabis has absolutely no benefit for treating PTSD." The Missourian adds that "cannabis mandated by the U.S. government through the National Institute on Drug Abuse has been described as sub-standard."

Regulators, Industry Trying To Properly Classify Cannabis Synthetics.

The Spokane (WA) Spokesman-Review (9/3, Eastwood, 187K) reports that "frustration and confusion are high in the cannabis industry nationally due to how to properly classify and regulate products made by chemically modifying the cannabis plant, including one method that creates a compound known as Delta 8." Currently, "15 states have banned sales of Delta 8 products out of concern for consumer safety." Meanwhile, "Washington's Liquor and Cannabis Board has spent much of this year learning about Delta 8 and what role it can or should play in regulating it." In May, "the LCB staff issued a notice that it was considering entering a rulemaking process regarding additives other than Delta 9." In July, "the LCB released a statement clarifying that licensed cannabis processors aren't allowed to convert CBD into Delta 9 THC." Meanwhile, "opponents of synthetics say their concern isn't so much the economic competition: it's the unknowns."

Young Adults Who Use Cannabis More Likely To Suffer Heart Attacks, Study Finds.

The Hill (9/7, Castronuovo, 5.69M) reports a new study found "young adults who have recently used marijuana may be more likely to experience a heart attack, with the risk even greater for frequent users." The study "included Centers for Disease Control and Prevention health data from more than 33,000 adults ages 18 to 44," and found "roughly 1.3 percent of the approximately 17 percent of adults who reported using cannabis within the previous 30 days said they later had a heart attack," compared to just 0.8% of non-users. What's more, the "association between marijuana use and heart attacks was consistent across different methods of consumption, including smoking, vaping and eating edibles." The findings were published Tuesday by the Canadian Medical Association Journal.

Biden's Drug Czar Wants To Make It Easier To Research Marijuana, Psychedelics And Other Schedule I Substances.

Marijuana Moment (9/3, Jaeger) reported that the White House Office of National Drug Control Policy (ONDCP) "proposed a change to the federal drug scheduling system on Thursday that it hopes will streamline research into Schedule I controlled substances including marijuana and psychedelics such as psilocybin." The ONDCP" said in a letter to congressional leaders and a plan posted on the agency's website that it wants to encourage research in part by simplifying the registration process for scientists to access Schedule I drugs so that they match those for less-restricted Schedule II substances." National Institute on Drug Abuse Director Dr. Nora Volkow has described the current registration system as "lengthy and cumbersome."

Vaping 'Significantly' Associated With Psychotic Experiences In U.S. College Students: Study.

The Regina (CAN) Leader Post (9/2, Stelmakowich, 181K) reports that "a new U.S. study reports that college students who vaped either tobacco or cannabis were more likely to report psychotic experiences." Researchers found "that about 14 per cent of the students reported psychotic experiences over the past year, a percentage in line with the estimated 14 to 15 per cent of participants who said they vaped over the past month." Meanwhile, "they are recommending that more prospective studies are needed to examine any association between vaping and psychotic experiences." The National Institutes of Health reported last fall "vaping marijuana and vaping nicotine rose sharply in the past three years among collegeage (19-22 years old) adults." NIAD Director Dr. Nora Volkow said, "Many young people may view vaping and cannabis use as 'safer', but the reality is that nicotine is highly addictive, and cannabis can also be addictive, particularly in younger adults for whom the brain is still developing."

Young People Who Vape May Be More Likely To Use Tobacco Cigarettes, Study Suggests.

The Guardian (UK) (9/9, Lu, 5.53M) reports, "Young people who use e-cigarettes are more likely to take up tobacco cigarettes, according to an international review of research into vaping." People under 20 "who used vapes were more than three times as likely to have ever smoked tobacco cigarettes, and more than twice as likely to have smoked cigarettes in the previous month, according to a review of 25 studies globally." The review, "published in the journal Plos One, was led by Australian researchers and funded by the World Health Organization."

FDA Faces September 9 Deadline To Rule On E-Cigarette Safety.

NPR (9/8, 3.69M) reports in a podcast that on September 9, "the FDA faces a deadline to decide which e-cigarettes are safe for the public and which might need to be removed." Kathleen Hoke, professor of public health law at the University of Maryland, discussed the deadline during the podcast. Hoke said "the primary question that the FDA faces is whether vape products, generally speaking without talking to a specific one, meet the public health standard that should allow them to be on the market." Hoke continued, "And that is whether they are, quote, 'appropriate for the protection of public health' – looking at the risks the products present, the benefits that they offer to the population as a whole."

Addicted America: Maintenance Treatments 'Widely Underutilized' For Drug Recovery In U.S.

WZTV-TV (9/2) reports that "maintenance treatments involve using medications, like methadone, an opioid, to help a patient beat addiction" and is "supported by several groups including The National Academy of Medicine, the American Medical Association, and the National Institute on Drug Abuse." In 2005, "the World Health Organization added methadone and buprenorphine to its list of essential medicines." According to the National Institute on Drug Abuse, "fewer than half of private-sector treatment programs offer maintenance treatments for opioid use disorders." NIDA Director Dr. Nora Volkow said, "To help people that are addicted to opioids actually protect them and eventually achieve recovery. ... The most effective intervention that we have." Volkow "says studies show that abstinence-only recovery options lead to higher rates of relapse and self-harm."

Rise Of Fentanyl-Laced Cocaine As Dealers Spike Drugs To Rake In Cash.

The Sun (UK) (9/6, Bradford, Allen, 561K) reports, "Comics Fuquan Johnson and Enrico Colangeli, who died along with a third friend in LA on Saturday, are thought to be the latest" unsuspecting victims to overdose "on deadly fentanyl secretly mixed into cocaine by ruthless dealers in a new scourge claiming lives across America." According to the article, "Drug overdose deaths have surged across the US throughout the Covid-19 pandemic, jumping by 30 percent, according to Vox."

NIDA Director Dr. Nora Volkow told the outlet, "This is completely different. It's a disruption of the trend." Volkow "said deaths involving fentanyl 'grew exponentially."

Additional Source. Newsweek (9/6, Georgiou, 2.67M) also covers the story.

Clinical Trials For Experimental Vaccine Against Opioid-Use Disorders Underway.

The Minneapolis Star Tribune (9/7, Olson, 855K) reports "clinical trials are underway to test the safety and effectiveness of an experimental vaccine developed at the University of Minnesota Medical School against opioid-use disorders." University "researchers hope the first-of-its-kind vaccine will counter the rapid growth in U.S. overdose deaths – which accelerated during the pandemic – but said recruitment for the intensive trial in New York has been a challenge since it launched last fall." The first "trial (known as a phase 1 trial in the run-up toward approval by the U.S. Food and Drug Administration) is seeking 45 participants to prove that the vaccine can be safely tolerated and to provide initial evidence of an effective immune response."

EDITORIAL: The Closing Of Methadone Mile 'Comfort Station' Is A Life Or Death Issue.

In an editorial, the Boston University (MA) Daily Free Press (9/3, 11K) says "The Methadone Mile' is a strip of land near Massachusetts Avenue and Melnea Cass Boulevard known to be populated by individuals with substance abuse issues." Boston "has made multiple attempts to dismantle the Methadone Mile since" 2014. The Daily Free Press says it's "important to acknowledge the difference between how drug use is treated on college campuses versus how it is treated on the Methadone Mile" and that "a 2018 survey from the National Institute on Drug Abuse found that college students are more likely to misuse Adderall – a drug somewhat chemically similar to meth – and cocaine." The Daily Free Press concludes that "politicians should create more substantial plans that provide actual treatment options rather than criminalizing substance abuse and removing essential resources that mean life and death for a lot of the residents of this area."

FDA Explores Ways To Bring Consistency To Opioid Safety Program Amid Overdose Spike.

Bloomberg Law (9/8, Baumann, Subscription Publication, 4K) reports, "The FDA is exploring ways to bring consistency to the opioid safety training that drugmakers must provide for prescribers as the opioid overdose epidemic continues to ravage the nation." The agency "announced Wednesday plans to hold a two-day public workshop next month to reconsider its drug safety program known as Risk Evaluation and Mitigation Strategy (REMS) for opioids." According to the article,

"Under the REMS program for opioids, companies that make these painkillers must provide unrestricted grants to continuing education providers."

Administration Proposes Removing Some Penalties For Fentanyl Trafficking.

Fox News (9/2, Dorman, 23.99M) reports that "the White House on Thursday proposed removing certain penalties associated with trafficking of fentanyl-related substances (FRS), prompting criticism that it would weaken illicit drug enforcement." Both "President Biden and former President Trump temporarily placed FRS under schedule I of the Controlled Substances Act" and "Thursday's proposal would make that change permanent while removing certain quantity-based mandatory minimums." In a letter to Senate leaders, "the Office of National Drug Control Policy (ONDCP) described the plan as the result of collaboration with the Justice Department (DOJ) and Department of Health and Human Services."

ONDCP acting Director Regina LaBelle said, "We are pleased to present to Congress a long-term, consensus approach that advances efforts to reduce the supply and availability of illicitly manufactured FRS, while protecting civil rights, and reducing barriers to scientific research for all schedule I substances."

Book Review: The Rise Of Harm Reduction In The War On Drugs.

Undark (9/3, Farah) reported, "Maia Szalavitz's new book 'Undoing Drugs: The Untold Story of Harm Reduction and the Future of Addiction' is an in-depth history of a powerful idea, exploring many angles of drug policy, including prescription drug use, supervised consumption, and legalizing cannabis." Throughout, Szalavitz "also details the racial inequities and social justice tensions that have defined the drug war." The article added, "The war on drugs may profess to be waged against narcotics, but it overwhelmingly targets people – a view increasingly shared by experts on drug use." NIDA Director Dr. Nora Volkow "touched on this recently when she wrote about addiction stigma in STAT, noting that 'societal norms surrounding drug use and addiction continue to be informed by myths and misconceptions."

Oregon Psilocybin Panel Teams Up With Harvard To Research Psychedelic History And Impacts Of Reform.

Marijuana Moment (9/6, Jaeger) reports that members of the Oregon Psilocybin Advisory Board, which is "charged with advising on the implementation of a legal psilocybin therapy program," have selected a team of researchers at "a recently established psychedelic research center at Harvard Law School" permission "to produce a comprehensive report on the science, history and culture of the psychedelic as regulators prepare to license facilities to administer it." According to the article, "Part of the intent of the new expanded research project is to help inform legislative efforts outside of Oregon where psychedelics reform is being considered." The National Institute on Drug Abuse is mentioned.

DIA:

Companies Announce FDA Acceptance Of NDA For Risperidone ER Injectable Suspension For Subcutaneous Use As Treatment For Schizophrenia

According to Healio (9/7), in an Aug. 31 press release, "Teva Pharmaceuticals and MedinCell announced FDA acceptance of a new drug application [NDA] for risperidone extended-release injectable suspension for subcutaneous use, a schizophrenia treatment." The agency "based its acceptance on data from two phase 3 pivotal studies that assessed the efficacy and long-term safety and tolerability of the schizophrenia treatment TV-46000/mdc-IRM."

Analysis: Telehealth Access Threatened As COVID-19 Emergency Orders Expire.

A Washington Post (9/4, Pasricha, 10.52M) analysis said telehealth opportunities, which "flourished" during the COVID-19 pandemic, "are being steadily pared away." The Post added that "as the second summer of the pandemic wanes, state emergency orders that mandate coverage of telehealth visits and waive the requirement for out-of-state medical licenses are expiring." Consequently, the Post said, "more patients are discovering that telemedicine is no longer an option for them," and "with a fourth wave of coronavirus cases surging, the safety of in-person visits, especially for immunocompromised patients, remains a concern." HHS Secretary Xavier Becerra was mentioned.

Seattle Overdose Task Force Calls For Decriminalization Of All Drugs.

Filter (NY) (9/2, Adlin) reports that "in response to the Seattle City Council's request for policy advice on how to curb overdose deaths, a local task force is recommending the widespread decriminalization of all drugs." The group said psychedelics in particular "could be a promising treatment to address substance use disorders and mental health issues." Meanwhile, report provisions of "House-passed spending legislation also touch on the need to expand cannabis and psychedelics research," urging "the National Institute On Drug Abuse to support expanded marijuana studies, for example."

Funding Opportunities



RFA-DA-22-040

High Priority HIV and Substance Use Research (R01 Clinical Trial Optional)

RFA-DA-22-028

<u>Pharmacokinetics (PK) and Pharmacodynamics (PD) of THC in Cannabis and Cannabis Products (R01 - Clinical Trial Optional)</u>

RFA-DA-22-039

<u>Pharmacokinetics (PK) and Pharmacodynamics (PD) of THC in Cannabis and Cannabis Products (R21 - Clinical Trial Optional)</u>

NOT-AT-21-017

Notice of Intent to Publish a Funding Opportunity Announcement for HEAL Initiative: Sickle Cell Disease Pain Management Trials Utilizing the Pain Effectiveness Research Network Cooperative Agreement (UG3/UH3, Clinical Trial Required)

NOT-AT-21-018

Notice of Intent to Publish a Funding Opportunity Announcement for HEAL Initiative: Pragmatic and Implementation Studies for the Management of Sickle Cell Disease Pain (UG3/UH3, Clinical Trials Optional)

The Alkermes Pathways Research Awards®

The Alkermes Pathways Research Awards® program provides opportunities for individual grants of up to \$100,000 per research project for early-career investigators focused on research relating to schizophrenia, bipolar disorder, alcohol use disorder (AUD) or opioid use disorder (OUD).

Application period opens: Sept. 13, 2021 - Application deadline: Nov. 12, 2021 (by 11:59 p.m. ET)

Alkermes Investigator Sponsored Studies

Alkermes seeks to support research designed and conducted by independent clinicians and scientists through our Investigator Sponsored Studies (ISS) program. The ISS program reviews study concept submissions related to Substance Use Disorders and Schizophrenia. Alkermes may occasionally announce a Request for Proposals (RFP) for research in clinical areas where gaps in data have been identified. Submission deadlines for any RFP topics will be announced on this site. The ISS research Alkermes supports must be based in the United States and is typically conducted by experienced researchers who have an established history of successfully completing research with independent funding. Please view details on the ISS program by using this link.

CAR Member New Publications

Computer-based alcohol reduction intervention for alcohol-using HIV/HCV coinfected Russian women in clinical care: study protocol for a randomized controlled trial Ralph J. DiClemente, Jennifer L. Brown, Ariadna Capasso, Natalia Revzina, Jessica M. Sales, Ekaterina Boeva, Lyudmila V. Gutova, Nadia B. Khalezova, Nikolay Belyakov & Vadim Rassokhin

Trials Journal,

DOI: https://doi.org/10.1186/s13063-021-05079-x

ABSTRACT

Background: Russia has a high prevalence of human immunodeficiency virus (HIV) infections. In 2018, over one million persons were living with HIV (PLWH); over a third were women. A high proportion of HIV-infected women are co-infected with hepatitis C virus (HCV), and many consume alcohol, which adversely affects HIV and HCV treatment and prognosis. Despite the triple epidemics of alcohol use, HIV and HCV, and the need for interventions to reduce alcohol use among HIV/HCV co-infected women, evidence-based alcohol reduction interventions for this vulnerable population are limited. To address this gap, we developed a clinical trial to evaluate the efficacy of a computer-based intervention to reduce alcohol consumption among HIV/HCV co-infected women in clinical care.

Methods: In this two-arm parallel randomized controlled trial, we propose to evaluate the efficacy of a culturally adapted alcohol reduction intervention delivered via a computer for HIV/HCV co-infected Russian women. The study population consists of women 21–45 years old with confirmed HIV/HCV co-infection who currently use alcohol. Intervention efficacy is assessed by a novel alcohol biomarker, ethyl glucuronide (EtG), and biomarkers of HIV and HCV disease progression. Women are randomized to trial conditions in a 1:1 allocation ratio, using a computer-generated algorithm to develop the assignment sequence and concealment of allocation techniques to minimize assignment bias. Women are randomized to either (1) the computer-based alcohol reduction intervention or (2) the standard-of-care control condition. We will use an intent-to-treat analysis and logistic and linear generalized estimating equations to evaluate intervention efficacy, relative to the standard of care, in enhancing the proportion of women with a laboratory-confirmed negative EtG at each research study visit over the 9-month follow-up period. Additional analyses will evaluate intervention effects on HIV (viral load and CD4+ levels) and HCV markers of disease progression (FibroScan).

Discussions: The proposed trial design and analysis provides an appropriate conceptual and methodological framework to assess the efficacy of the computer-based intervention. We propose to recruit 200 participants.

The intervention, if efficacious, may be an efficient and cost-effective alcohol reduction strategy that is scalable and can be readily disseminated and integrated into clinical care in Russia to reduce women's alcohol consumption and enhance HIV/HCV prognosis.

© [2020 Center for Addiction Research]



